SCOPE OF PRACTICE
FOR
VA RESEARCH STAFF
(Not for use by Principal Investigator)

VA MARYLAND
HEALTH CARE SYSTEM

This Research Scope of Practice is specific to the duties and responsibilities of the individual as a research team member of the listed principal investigator (PI). As such he/she is specifically authorized to conduct research involving human subjects, animal subjects, laboratory specimens, and or data with the responsibilities outlined below. The team member is authorized to perform the same duties in other studies. The PI must review Sections I and II with the staff member and complete Section III. Please refer to the "Research Scope of Practice for Research Staff/Personnel INSTRUCTIONS/GUIDANCE" for assistance in accurately completing this form.

SECTION I: GENERAL INFORMATION

Research Staff Member Name (please print)	**Principal Investigator Name (please print)**
Research Role	**Type of Research (check all that apply):**
☐ Sub-investigator ☐ Research Scientist ☐ Team Member ☐ Study Coordinator ☐ Technician ☐ Data Manager/Statistician ☐ Trainee(i.e. Fellow/Resident/Student…) ☐ Other:_____	☐ Human Subjects Research ☐ Animal research ☐ Laboratory research ☐ Data only research ☐ Other:_____

For Human Subjects Research:	
Interaction with Participants	**Licensure Status**
☐ Direct participant contact not involving invasive procedures ☐ Direct participant contact involving invasive procedures ☐ No direct participant contact but handle PHI ☐ No patient contact or PHI	Are you a licensed professional? ☐ YES ☐ NO If yes, indicate type of license: ☐ MD; ☐ PhD; ☐ DNP; ☐ NP/PA; ☐ RN; ☐ LPN; ☐ None; ☐ Other:_____
Status of VA Credentialing and Privileging	
Will you be performing activities in your research study roles that require clinical credentials? ☐ YES ☐ NO If yes, do you have a clinical scope of practice or functional statement that includes those activities? ☐ YES ☐ NO **If no, you must obtain clinical credentials before applying for these activities as part of your Research Scope of Practice**.	

SECTION II: DELEGATION OF DUTIES

The above individual is authorized to perform the following duties/procedures on a regular and ongoing basis.

IIA. Routine Duties: Human Subjects Research	Requested	Approved
1. Initiates submission of regulatory documents to the IRB, VAMHCS R&D Committee, and the study sponsor as required.		
2. Prepares study initiation activities.		
3. Develops and/or implements recruitment methods to be utilized in the study.		
4 Accesses PHI, screens patients to determine study eligibility criteria by reviewing patient medical information or interviewing subjects.		
5. Provides education and instruction on study medication use, administration, storage, and side effects.		
6. Is authorized to obtain informed consent from research subject and is knowledgeable to perform the informed consent "process".		
7. Provides education regarding study activities to participant, relatives/caregivers and Medical Center staff as necessary per protocol.		
8. Maintains complete and accurate data collection in case report forms and source documents.		
9. Initiates and/or expedites requests for consultation, special tests or studies following the Investigator's approval.		
10. Obtains and organizes data such as test results, diaries/card or other necessary information for the study.		
11. Accesses or uses CPRS computer system for research purposes.		
12. Monitors participant's clinical condition and reports findings. (The individual is trained/qualified to "monitor" clinical signs and know when to report to medical staff [vs. someone who only records VS but does not monitor/interpret/make decisions pertaining to clinical signs])		
13. Administers questionnaires or conducts mental status or psychosocial exams		
14. Performs venipuncture to obtain specific specimens required by study protocol (requires demonstrated and documented competencies)		
15. Initiates intravenous (IV) therapy as covered by privileges from VAMHCS Professional Standards Board or a functional statement. (Please append)		
16. Administers medications as covered by privileges from VAMHCS Professional Standards Board or a functional statement. (Please append)		
17. Collects and handles various types of human specimens.		
18. Performs packaging, transporting, and shipping of human blood, blood components, tissues, or other body fluids and does so in research.		
19. Reports adverse events to the IRB, RDC and sponsors according to protocol.		
20. Inputs data into CICERO and submits to VAMHCS committees		
Other duties not listed above but included in IRB/RDC approved protocol, (for example: invasive procedures):		
21.		
22.		
23.		
24.		
25.		

IIB. Routine Duties: Animal Research	Requested	Approved
1. Conducts research involving live or dead animals or their unfixed tissues (organs, skin, blood, cultures, etc.) or products (urine, feces, other body fluids, cell lines, etc.).		
2. Plans/conducts research involving rodents		
3. Plans/conducts research involving dogs or cats (attach documentation of qualifications)		
4. Plans/conducts research involving non-human primates (attach documentation of qualifications).		
5. Plans/conducts research involving other animal species: Specify:_____		
Other duties not listed above but included in IACUC/RDC approved protocol:		
6.		
7.		
8.		
9.		
IIC. Routine Duties: Laboratory Research	**Requested**	**Approved**
1. Uses and stores chemicals.		
2. Operates laboratory equipment		
3. Uses and stores biological materials (for example: tissues, secretions, cell lines, microbiological or viral agents, pathogens or toxins, recombinant or synthetic DNA, etc.)		
4. Uses radioactive materials and/or radiation generating equipment.		
5. Uses controlled substances		
6. Collects, records, or analyzes research data.		
7. Processes and ships infectious and or biological materials.		
Other duties not listed above but included in SRS/RDC approved protocol:		
8.		
9.		
10.		

SECTION III: CERTIFICATIONS

PRINCIPAL INVESTIGATOR STATEMENT:

This Research Scope of Practice was reviewed and discussed with the staff member whose signature is given below. After reviewing his/her education, clinical competency, qualifications, research practice involving human subjects, animal subjects, laboratory skills, peer reviews, and individual skills. I certify that he/she possesses the skills to safely perform the aforementioned duties/procedures. The above named individual and I are familiar with all duties/procedures granted or not granted in this scope of practice. We agree to abide by the parameters of this Scope of Practice and all applicable hospital policies and regulations.

The research staff member will not begin research activities until this document has been approved by the ACOS for R&D. This Scope of Practice will be reviewed and replaced as needed to reflect any changes in the staff member's duties or changes in regulations.

Principal Investigator Signature _____ Date _____

Staff Member Signature _____ Date _____

ACOS for R&D STATEMENT:

I have reviewed this Research Scope of Practice and find it appropriate based on the information provided and the attestations of the Principal Investigator and Staff Member. This Research Scope of Practice is valid until the staff member's duties change.

ACOS/R&D Signature _____ Date _____